

### REMARKS

Claims 55-100 currently are pending. Claims 1-54 have been canceled. The subject matter of claims 1-54 potentially will be pursued in a divisional application.

#### **Specification**

The examiner objected to the specification because it lacks a brief description of the drawings. In response, applicants add a brief description of the drawings to the specification.

Applicants correct the abstract of the disclosure so that it is in a single paragraph. The new abstract is attached on separate sheet.

#### **Claim objections**

Claims 6 and 49 were objected to for reciting nonelected inventions. Claims 1-54 have been canceled. New claims (55-100) all are drawn to the elected invention: promoter of the plant V-ATPase subunit c isoform 2 as shown in SEQ ID NO: 1.

Claim 31 has been canceled. The subject matter of claim 31 now is covered by claim 80. Claim 80 has an article before the word "method."

#### **35 USC § 112, first paragraph**

Claims 1, 3-5, 7, 9-10, 13-23 and 51-54 were rejected under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The examiner stated that the claimed genus including those yet to be discovered and that

the disclosure of only three plant V-ATPase promoters from a single plant species does not provide an adequate description of the claimed genus, and in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus that comprises plant V-ATPase promoters.

In the office action (paper no. 9), the examiner stated on page 5, lines 10-11 that the specification is enabling for the elected promoter of the *B. vulgaris* plant V-ATPase subunit c isoform 2 set forth in SEQ ID NO: 1. New claims 55-74 and 97-100 cover the subject matter of the above rejected claims. The new claims only are directed to a promoter of the plant V-ATPase subunit c isoform 2 and not to plant promoters of the complete V ATPase gene family. Therefore, applicants believe the 112 first paragraph rejection has been overcome.

**35 USC § 112, second paragraph/ 35 USC § 101**

Claims 1, 3-7, 9-11, 13-28, 31-36, 39-41, 43-44, 49 and 51-54, and claims 29-30 and 37-38 were rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 was indefinite in the recitation of "with" before "a plant V-ATPase promoter. Claim 55 which replace claim 1 recites "A DNA construct comprising the promoter of the plant V-ATPase subunit c isoform 2..."

Claim 1 was indefinite in the recitation of "its functional equivalent." Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of

the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. MPEP § 2173.02. The specification on page 14 at lines 23-25 defines the term "functional equivalents." The term "functional equivalents" characterizes all DNA sequences which are complementary to a DNA sequence, which hybridize with the reference sequence under stringent conditions and which show an activity which is similar to that of a plant V-ATPase promoter. Interpreting claim language in light of the specification is permissible and is not reading limitations of the specification into the claim. Applicants remind the examiner that some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. MPEP § 2173.02.

Claims 1, 10, 24, 28, 43, and 44 were indefinite in the recitation of a "gene." The specification on page 14, lines 35-37 defines heterologous genes as "isolated DNA sequences which encode peptide or proteins which are other than the plant V-ATPase subunits A, c1 or c2." Interpreting claim language in light of the specification is permissible and is not reading limitations of the specification into the claim.

Claims 3-5, 18-19, 25-27 and 33-35 were indefinite in the recitation of "derived." The examiner believed it is unclear how much of the promoter is derived from plants, or how much of the cell or protoplast is derived from a plant. New claims 55-100 recite "obtained" instead of "derived."

The new claims which replace claims 3-7, 9-10, 13-15, 17, 20, 24, 28, 40, 41, 43 and 51-54 recite "the DNA."

New claim 58, which replaces claim 5 recites "obtained from plants selected from the group consisting of"

New claim 58 depends on claim 55, therefore the recitation in claim 58 of dicotyledonous as well as monocotyledonous plant species is permissible.

New claims 62 and 95 (which replace claims 11 and 49) do not use brackets. Claim 6 has been canceled.

Claims 7, 13 and 20 were indefinite in the recitation of "encompasses." The claims which replace claims 7, 13 and 20 recite "additionally comprises" instead of "encompasses."

Claim 7 was indefinite in the recitation of "different manner." Claim 59 replaces claim 7. Whichever manner the first promoter is regulated, the second promoter should be regulated in a different manner. Manner of the first promoter need not be defined.

Regarding the recitation of specific heterologous genes in claim 10, "wherein the heterologous gene is A, B, C, D or E" is proper Markush format.

Claim 10 was indefinite in the recitation of "a resistance-mediating gene." Applicants believe this term is understood by one of ordinary skill in the art.

Claim 10 was indefinite in the recitation of "other medicinal, agronomical or other interest." The selection marker and the resistance-mediating gene do not fall within one of these categories. This is why the claim recites "other medicinal, agronomical or other

interest.”

Claim 11 was indefinite in the recitation of “its functional equivalent.”

Replacement claim 62 now recites “the functional equivalent of this promoter.” As argued above the term “functional equivalents” characterizes all DNA sequences which are complementary to a DNA sequence, which hybridize with the reference sequence under stringent conditions and which show an activity which is similar to that of a plant V-ATPase promoter. (specification, page 14, lines 23-27)

Claim 62 recites “comprising” instead of “encompassing.”

Claim 67 which replaces claim 35 recites “the recombinant vector.”

Claims 68, 69, and 70 recite “a transgenic plant cell or transgenic protoplast.”

Claims which replace 18-19 and 21-23 all recite “the transgenic” instead of “a transgenic.”

The examiner believes there is insufficient antecedent basis in claims 21, 25, 29 and 37 for dicotyledonous plant species. New claims 74, 78, 82 and 90 depend on claim 71 which provides antecedent basis for a transgenic plant including both dicotyledonous and monocotyledonous plant species.

Claims 24 and 28 were indefinite in the recitation of “controlled.” In replacement claims 75 and 79, applicants delete the term “controlled.”

Claims 24, 28, 32 and 36 were indefinite in the recitation of “such.” With the new replacement claims 75, 79, 83, and 87, applicants remove the recitation of “such.”

Claims 24, 28, 32, 36, 43, 51 and 53 were indefinite in the recitation of “a biotic

or abiotic stress." To overcome the rejection applicants delete "biotic or abiotic" in the corresponding new claims.

Claims 28 and 36 were indefinite in the recitation of "to give rise to." In the corresponding new claims applicants change "to give rise to" to "to produce."

Claims 32 and 36 were indefinite in the recitation of "the recombinant protein transformed by means of the DNA construct is expressed." Applicants follow the examiner's suggestion to recite "the DNA construct expresses the recombinant protein" in corresponding new claims 83 and 87.

The examiner stated that there was insufficient antecedent basis in claim 33 for "process." Claim 86 which replace claim 35 recites "The method."

Claims 40-41, 43-44 and 49 were rejected as improper use claims. The corresponding new claims are 91-92, 93-94, and 95. These new claims are method claims which recite a definite step.

### **35 USC § 102**

Claims 1, 3-7, 9-11, 13-17, 19, 24-26, 32, 34, 40 and 51 were rejected under 35 USC § 102(b) as being anticipated by Struve et al. (The Journal of Biological Chemistry, Vol. 265, No. 14, May 15, 1990, pages 7927-7932) because Struve et al. teach a DNA construct with the dicotyledonous carrot plant V-ATPase promoter operatively linked to a heterologous GUS gene, said construct encompassing a second NOS promoter which can be regulated in a different manner, an expression cassette, a recombinant vector, and a shuttle vector, a microorganism transformed with the recombinant vector,

a dicotyledonous transgenic carrot plant cell whose genome encompasses the DNA construct, and the use of the DNA construct for producing a recombinant GUS protein in transgenic carrot plant cells.

Struve et al. disclose an expression cassette comprising the promoter of the catalytic V-ATPase subunit A operatively linked to a heterologous GUS gene, but it does not disclose an expression cassette comprising the promoter of the subunit C (isoform 2) operatively linked to a reporter gene. Also, Struve et al. do not disclose the upregulation of the expression of a heterologous gene that is under control of the promoter derived from a gene of the V-ATPase gene family.

New claims 55-68, 70, 75-77, 83, 85, 91, and 97 cover the subject matter of claims 1, 3-7, 9-11, 13-17, 19, 24-26, 32, 34, 40 and 51. The new claims only are drawn to the sequences of a plant promoter of V-ATPase subunit c isoform 2. As such, the new claims are not anticipated by Struve et al.

Claims 55 and 62 also are drawn to "functional equivalents" of a plant promoter of V-ATPase subunit c isoform 2.

The DNA constructs comprising the promoter of the catalytic V-ATPase subunit A prepublished in Struve et al. cannot be considered as "functional equivalents" of a plant promoter of V-ATPase subunit c isoform 2 for the following reasons.

A definition of the term "functional equivalent" is given on page 14, lines 23 to 33 of the specification: the term "functional equivalent" characterizes all DNA sequences which are complementary to a DNA sequence, which hybridize with the reference

sequence under "stringent conditions" and which show an activity which is similar to that of a plant V-ATPase promoter.

"Stringent conditions" are defined as those conditions under which hybridization takes place, and remains stable at 60°C in 2.5 \* SSC buffer followed by repeated washing steps at 37°C at a lower buffer concentration.

Since the sequence homology between the promoter sequences of *B. vulgaris* V-ATPase subunit c isoform 2, which is claimed, and the promoter sequence of the *B. vulgaris* V-ATPase subunit A, which is disclosed in Struve et al., is rather weak, as shown in the sequence listing, the nucleic acid molecules containing the promoter of subunit A and containing the promoter of subunit c isoform 2 would not hybridize with each other under the "stringent conditions" defined on page 14 of the specification.

### **35 USC § 103**

Claims 18, 20-23, 25, 27-31, 33, 35-39, 41, 43-44 and 53 were rejected under 35 USC 103(a) as being unpatentable over Struve et al. because although Struve et al. do not teach monocotyledonous transgenic plant cells, or monocotyledonous or dicotyledonous transgenic plants, it would be have prima facie obvious to transform and regenerate both monocotyledonous and dicotyledonous plants with a plant V-ATPase promoter operatively linked to a heterologous gene, for the purpose of producing a recombinant protein in a plant, without any surprising or unexpected results.

As stated above, claims 55-68, 70, 75-77, 83, 85, 91 and 97 are drawn to DNA constructs comprising the promoter of the ATPase subunit c isoform 2. Applicants



believe the sequence of the promoter of the ATPase subunit c isoform 2 is novel and since this promoter sequence shows a rather weak sequence homology to the promoter of the ATPase subunit A that was anticipated by Struve et al., a DNA construct comprising a promoter of the ATPase subunit c isoform 2 is not obvious to a person of ordinary skill in the art.

The object of the present invention is to provide DNA constructs comprising promoters which show a strong constitutive gene expression that is up-regulated by salt stress or by other biotic or abiotic stress factors, preferably by stress by vulneration.

Since a gene that is expressed under control of the promoter of the ATPase subunit c isoform 2 is upregulated under salt stress and under abiotic or biotic stress factors, as vulneration (fig. 9-12), this object has been achieved by the DNA constructs of the invention. The upregulation of genes that are expressed under control of the promoter of the ATPase subunit under salt stress or under abiotic or biotic stress factors, as vulneration, has not been disclosed in Struve et al. Therefore, this stress-dependent regulation also is not obvious to a person of ordinary skill in the art.

Thus, the objects of claims 55 to 100, in particular the DNA constructs of claims 55-61, should not be obvious to a person of ordinary skill in the art, regardless of whether monocotyledonous or dicotyledonous plants are transformed by the DNA constructs of the invention.

For the reasons expressed above, it is urged that the prior art references cited by the examiner either singly or in combination fail to anticipate or suggest the present

invention as defined by the amended claims. Accordingly, a *prima facie* case of obviousness has not been established by the examiner, and the rejection under 35 USC § 103 should be withdrawn.

**A check in the amount of \$110.00 is attached for a one-month extension fee.**

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such deposit account.

Respectfully submitted,

KEIL & WEINKAUF

A handwritten signature in cursive script, appearing to read "Daniel Kim".

Daniel S. Kim  
Reg. No. P-51877

1350 Connecticut Ave., N.W.  
Washington, D.C. 20036  
(202)659-0100

DSK/kas

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE ABSTRACT**

Replace the abstract on page 63 with the attached new abstract.

**IN THE SPECIFICATION**

Page 5, line 32, insert the following:

--BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic representation of the construct pBVA-70(16)/GUS and pBVA-70(16)/LUC.

FIG. 2 shows the construction of the construct pBVA-70/LUC.

FIG. 3 shows the construction of construct pBVA-16/LUC.

FIG. 4 shows the BVA/16-2 promoter deletions.

FIG. 5 shows the BVA/16-1 promoter deletions.

FIG. 6 shows the comparison of the activity of different promoters under control conditions.

FIG. 7 shows a Northern blot analysis on the expression of the c2 isoform in *Beta vulgaris*.

FIG. 8a and 8b show the comparison of the activities of different deleted promoters under control conditions.

FIG. 9 shows the Northern blot analysis that the transcript quantities for the V-ADTase genes A, c1 and c2 after exposure to salt are all elevated compared with the

control treatment.

FIG. 10 shows the Northern blot analysis for detecting the gene expression of V-ATPase and V-PP<sub>ase</sub> in storage parenchyma cells of sugar beet after mechanical wounding.

FIG. 11 shows the Western blot analysis with a polyclonal antiserum against the *K. daigremontiana* V-ATPase holoenzyme and shows wound-induced changes in V-ATPase on the tonoplast in the storage parenchyma of the sugar beet.

FIG. 12 shows wound-induced changes in the H<sup>+</sup>-pump activity of the V-ATPase in the microsomal and in the enriched tonoplast fraction in the presence of 100  $\mu$ M vanadate and 1 mM azide.--

Page 42, amend the paragraph on lines 15-31 to read as follows:

[Figure 8 shows] Figures 8A and 8B show the comparison of the activities of different deleted promoters under control conditions. In this experiment with the transient gene expression by means of the ballistic transformation, the activities of the individual promoters are determined indirectly by the luciferase activity. The deleted V-type H<sup>+</sup>-ATPase promoters BVA/16-1 and BVA/16-2 are compared with the CaMV 35S promoter. The end values of the luciferase activities are corrected with regard to each other by a cotransformation with the construct pFF19G. The diagram shows the corrected end values

with the standard deviations. The numbers beneath the columns refer to the various deletion fragments shown in Figures 4 and 5.

**IN THE CLAIMS**

Cancel claims 1-54.

Add new claims 55-100 as shown on the previous "CLEAN VERSION OF AMENDMENTS."